PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 5/00, A61F 2/02 — A1

(11) International Publication Number: **WO 00/32092**

(43) International Publication Date: 8 June 2000 (08.06.00)

(21) International Application Number: PCT/US99/28024

(22) International Filing Date: 24 November 1999 (24.11.99)

(30) Priority Data:
60/110,106 25 November 1998 (25.11.98) US

(71) Applicant *(for all designated States except US)*: BALL SEMICONDUCTOR, INC. [US/US]; 415 Century Parkway, Allen, TX 75013 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: ISHIKAWA, Akira [JP/US]; 846 FM 2453, Royce City, TX 75189 (US). TAKEDA, Nabuo [JP/JP]; 2-38-7 Nishinodaira, Taihaku-ku, Sendai-si, Miyagi-ken 982-0825 (JP). AHN, Suzanne, I. [US/US]; 7918 Glen Albens Circle, Dallas, TX 75225 (US). AHN, Samuel, S. [US/US]; 256 South Beverly Glen, Los Angeles, CA 90024 (US). HAYS, Steven, R. [US/US]; 7918 Glen Albens Circle, Dallas, TX 75225 (US). GAFFNEY, F., Andrew [US/US]; 6613 Chatsworth Place, Nashville, TN 37205-3955 (US).

(74) Agent: HOWISON, Gregory, M.; Thompson & Howison, L.L.P., P.O. Box 741715, Dallas, TX 75374-1715 (US).

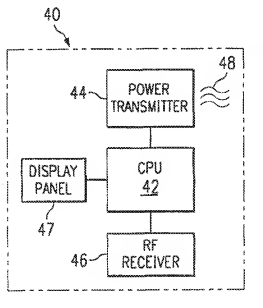
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: INTRALUMINAL MONITORING SYSTEM

(57) Abstract

A monitor (10) for detecting various parameters of a patient's vascular and luminal systems, is implanted in the body as part of another medical device, such as a stent, graft, intravascular filter, or A–V fistula. The monitor (10) includes integrated circuitry fabricated on a miniature spherical semiconductor device or ball, and which can be incorporated into arrays of such balls. The integrated circuitry of the monitor (10) contains a power coil (28) for coupling low frequency electromagnetic radiation (48) from a power transmitter (44) of an external station (40). The power coil (28) passes the received power to a power regulator (30) for power regulation to onboard circuits, such as a processor (32). The monitor (10) includes a transducer (26) to detect bloodstream conditions or other parameters, such as pressure and flow rate. The parameters are converted to data signals by the processor (32) and are modulated onto an RF carrier frequency signal for transmission (50) by an RF transmitter (34) to an RF receiver (46) of the external station (40). The CPU (42) then extracts and processes the data from the high frequency signal, and displays on a display panel (47) the bloodstream parameters for observation by the patient or a medical professional. In an alternative embodiment, the monitor (10) includes its own miniature source.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INTRALUMINAL MONITORING SYSTEM

TECHNICAL FIELD OF THE INVENTION

This invention is related to body implantable systems, and more particularly to miniature electronic components for monitoring the performance of intraluminal devices such as stents, grafts, and vascular filters.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119(e) from U.S. Provisional Patent Application Serial No. 60/110,106 filed on November 25, 1998, having the same title as this application.

This application is related to co-pending U.S. Patent Application Serial No. 09/323,585 (Atty. Dkt. No. BASI-24,635) entitled "IMPLANTABLE EPICARDIAL ELECTRODE," filed on June 2, 1999; U.S. Provisional Patent Application Serial No. 60/137,071 (Atty. Dkt. No. BASI-24.658) entitled "GLUCOSE SENSOR," filed on June 2, 1999; U.S. Patent Application Serial No. _____ (Atty Dkt. No. BASI-24,784) entitled "SPHERICALLY-SHAPED BIOMEDICAL IC," filed of even date herewith; U.S. Patent Application Serial No. _____ (Atty. Dkt. No. BASI-24,785) entitled "MINIATURE SPHERICAL-SHAPED SEMICONDUCTOR WITH TRANSDUCER," filed of even date; U.S. Patent Application Serial No. _____ (Atty Dkt. No. BASI-24,787) entitled "INTERNAL THERMOMETER," filed of even date herewith; U.S. Patent Application Serial No. _____ (Atty Dkt. No. BASI-24,789) entitled "MONITOR FOR INTERVENTIONAL PROCEDURES," filed of even date herewith.

BACKGROUND OF THE INVENTION

Recent advances in angioplasty have dramatically increased the use of intraluminal stents in the treatment of atherosclerosis and vessels narrowed by stricture development. Inflammatory conditions or malignancies can cause strictures to develop in other luminal vessels such as the tracheobronchial tree, urethra, pancreatic-biliary ducts, and gastrointestinal and urological luminal systems. Such strictures are also treatable using intraluminal stents. Blood vessels partially occluded by tumor invasion may also benefit from balloon dilation and stent placement.

Grafts and stent-graft combinations are widely used in the treatment of aortic aneurysms and arterial occlusive diseases. Various implantable filters can be employed for treatment of thromboembolic disease or for controlled drug delivery. Implantable intraluminal devices also include arteriovenous fistulas used in hemodialysis.

These and other applications of intraluminal medical techniques using implantable devices have given rise to a need for post-operative monitoring of such devices that heretofore has not been adequately addressed by conventional medical equipment and procedures.

SUMMARY OF THE INVENTION

The present invention disclosed and claimed herein, in one aspect thereof, is directed toward a monitoring system for use in sensing a condition within a body, and communicating with a station located outside the body. An intraluminal device is implanted within the body, the device having a wall defining a lumen. A miniature electronic monitor is secured to the device, the monitor having a transducer in communication with fluid adjacent the wall for sensing a quantitative condition of the fluid, and generating an electrical signal corresponding to the sensed quantitative condition. The monitor contains circuitry responsive to the electrical signal and for generating an electromagnetic wave corresponding to the electrical signal which is received by the station.

In another aspect of the invention, a method is disclosed for monitoring a parameter of the fluid flowing through an intraluminal device implanted within a living body. A monitor secured to the intraluminal device senses quantitative data representing a parameter of fluid flowing through the intraluminal device. The sensed data is then converted into electrical signals and the electrical signals modulated onto a high frequency carrier signal. The modulated carrier signal is transmitted outside of the body and received at an external station. The high frequency signal is demodulated to extract a parameter computed from the quantitative data. The quantitative data may then be optionally displayed.

In still another aspect of the invention, a system is disclosed which comprises the external monitoring station, and a miniature electronic monitor implanted in an intraluminal device. The external monitoring station comprises a central processing unit for processing all information obtained during the monitoring function, a power transmitter operating under the control of the central processing unit, the power transmitter being equipped to produce a low frequency electromagnetic field, and a radio-frequency receiver operating under the control of the central processing unit. The intraluminal device is implanted in a body; and contains the miniature electronic monitor, monitor having integrated circuitry which includes a processor, a power coil responsive to the low frequency electromagnetic field to provide electrical energy to the monitor, a transducer in communication with the processor for sensing a condition of the vascular system of the body, and a radio-frequency transmitter in communication with the processor for transmitting a modulated signal including data representing the condition sensed by the

transducer, the modulated signal being adapted to be received by the radio-frequency receiver of the monitoring station outside the body.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention and the advantages thereof, reference is now made to the following description taken in conjunction with the accompanying Drawings in which:

FIGURE 1 illustrates a schematic longitudinal cross section through a body vessel and stent, the stent including a monitor according to a disclosed embodiment;

FIGURE 2 illustrates an enlarged view of a portion of FIGURE 1 showing the monitor with a transducer thereon and adjacent portions of the adjoining stent;

FIGURE 3 illustrates a block diagram of a monitoring system according to a disclosed embodiment;

FIGURE 4A illustrates an enlarged cross section of a portion of the monitor of FIGURE 2 taken along lines 4-4 of FIGURE 2;

FIGURE 4B illustrates a greatly enlarged portion of the monitor of FIGURE 2 that includes the transducer;

FIGURE 4C illustrates a conventional strain gauge circuit according to the device structure of FIGURE 4B;

FIGURE 5 illustrates a cross section of a portion of a monitor similar to the monitor of FIGURE 4, but modified in accordance with a disclosed embodiment;

FIGURE 6A illustrates a schematic longitudinal cross section through a stent in accordance with another alternative embodiment that may be employed in an artery in lieu of the stent shown in FIGURE 1;

FIGURE 6B illustrates an LED/photodiode pair in operation according to the embodiment of FIGURE 6A, and depicting the device structures for use according to the embodiment of FIGURE 4A;

FIGURE 6C illustrates a conventional circuit diagram of the LED/photodiode circuit as fabricated and illustrated in FIGURE 6B;

FIGURE 7 illustrates a schematic longitudinal cross section through another alternate embodiment of an intraluminal monitoring system according to a disclosed embodiment;

FIGURE 8 illustrates a side elevation of a cluster of semiconductor balls that may be employed as a monitor;

FIGURE 9 illustrates a vertical sectional view through electrical contacts of the embodiment of FIGURE 8 taken along line 9-9 of FIGURE 8;

FIGURE 10 illustrates a schematic depiction of a cluster of semiconductor balls that have application in the context of a disclosed embodiment;

FIGURE 11 illustrates a schematic vertical cross section through an abdominal aortic aneurysm with an implanted graft shown in longitudinal cross section and including monitors in accordance with a disclosed embodiment;

FIGURE 12 illustrates a diagram of a patient's arm showing an arteriovenous fistula implanted beneath the skin and connected to an artery and a vein;

FIGURE 13 illustrates a cross section through a portion of the fistula of FIGURE 12 at a site of monitoring elements included therein;

FIGURE 14 illustrates a schematic block diagram of the receiver/transmitter and a detection/power system according to a disclosed embodiment;

FIGUREs 15A-15C illustrate alternative embodiments for the receiver/transmitter and the storage capacitors associated therewith;

FIGURE 16 illustrates a cross-sectional side view of the monitor in an alternate embodiment utilizing a local power source;

FIGURE 17 illustrates a schematic block diagram of the circuitry utilizing a battery as the primary power source;

FIGURE 18 illustrates a perspective view of one of the spherical semiconductor monitors having the antenna leads disposed thereon; and

FIGURE 19 illustrates a cross-sectional diagram of the portion of the surface of the spherical monitor ball of FIGURE 18.

DETAILED DESCRIPTION OF THE INVENTION

STENT MONITORING APPLICATIONS

A common treatment for atherosclerotic occlusive disease is intraluminal stent deployment at the site of a vascular stenosis. Catheter delivery systems and the use of balloon angioplasty for stent deployment are well known in the art. Unfortunately, the occurrence of restenosis to a significant degree in many cases necessitates patient monitoring and in some cases resort to secondary angioplasty procedures or even corrective surgical bypass operations. The disclosed embodiment provides an improved system for post-operative monitoring of the patency of intraluminal stents.

Additionally, luminal narrowing (stenosis) can occur as a result of localized sites of inflammation or tumor invasion in the tracheobronchial tree, pancreatic-biliary ducts, and gastrointestinal and urologic luminal systems. The stenosis may result in impaired function and possible failure of the organ system involved (lungs, pancreas, liver, and kidneys) with potential life-threatening implications. Medical treatment in such cases can include balloon dilation and placement of various implantable intraluminal devices at the affected site. The disclosed embodiment provides for an improved and less invasive means of monitoring the patency of these luminal systems.

Referring now to FIGURE 1, there is illustrated a monitor 10, according to a disclosed embodiment, in a cutaway view of a body vessel 12, specifically an artery, within which a stent 14 has been deployed at a site 16 of a stenosis. Except for the inclusion of the monitor 10, the stent 14 is conventional in construction and is shown after implantation within the lumen of the artery 12 using well-known techniques. Briefly, plaque 18 has accumulated on the interior of the artery 12, creating a stenosis or occlusive stricture requiring treatment. Stent-assisted angioplasty has been performed resulting in the condition schematically depicted in FIGURE 1.

As is well known in the art, a catheter delivery system (not shown) introduces the stent 14 in a radially compressed condition at the site 16. The catheter delivery system often includes a balloon (not shown) that is inflated to expand the stent 14 radially outward to the position illustrated in FIGURE 1. The stent 14 has a generally cylindrical wall 14a, which is sufficiently rigid to retain its shape after the balloon and associated catheter are removed. The successful deployment of the stent 14 forces the plaque 18 radially outward, slightly increasing the outside diameter of the artery 12 at the site 16. The open interior of the stent 14 reintroduces luminal patency and healthy blood flow through the artery 12.

Any of various conventional stents can be modified to include the monitor 10. Conventional stents typically comprise a network of wires woven into a cylindrical shape. Preferably, the wires of the stent consist of a nickel-titanium (NiTi) alloy commonly known as Nitinol, which has excellent shape-retention capability and other desirable properties. This is well known. The monitor 10 senses conditions within the artery 12, such as blood pressure, and communicates such information outside the patient's body.

Referring now to FIGURE 2, there is illustrated an enlarged view of the monitor 10 and its general construction. The monitor 10 preferably comprises a spherical-shaped semiconductor device on which an integrated circuit has been formed, although other materials such as organic semiconductor materials are envisioned. Such a spherical-shaped integrated circuit semiconductor device (sometimes referred to herein as a "ball" and a "spherical IC") is described in commonly-assigned U.S. Patent No. 5,995,776, filed May 16, 1997, and issued September 21, 19999, entitled "Spherical Shaped Semiconductor Integrated Circuit," which is hereby incorporated by reference. The diameter of such a spherical-shaped monitor 10 can be made very small, allowing it to be incorporated into the stent wall 14a without occlusion of the vessel lumen. For example, such ball monitors 10 can have diameters in the range from 0.1 to 1.0 millimeter. The spherical-shaped monitor 10 is retained in a socket 20, which is secured to the stent 14. The socket 20 is preferably made of a suitable plastic material, such as polyethylene or polytetrafluoroethylene, and conforms to the spherical exterior of the monitor 10. Alternatively, a suitable socket for the monitor 10 may be integrally formed as part of the stent, or the monitor can be attached directly to the stent. As previously mentioned, the preferred stent 14 is a metallic network of NiTi wires 22 woven into a cylindrical shape. The stent 14 may include lock rings 24 that fit into corresponding recesses in the socket 20 to secure the monitor 10 and socket 20 within the wall of the stent 14.

The monitor 10 has a thin glass exterior, which will be described more fully below. Regions of the monitor 10 are depicted within the dashed outlines in FIGURE 2. A transducer 26 disposed on the top of the monitor 10, in this particular embodiment, is in communication with the blood flowing through the artery 12. The transducer 26 senses a condition or parameter of the blood, such as pressure. In the specific case of pressure sensing, the transducer 26 preferably comprises a strain gauge integrated on the surface of the monitor 10 and electrically connected with other elements of the monitor's integrated circuitry. The transducer 26 converts the pressure of the blood that it senses into an electrical signal proportional to the pressure.

The transducer 26 and integrated circuitry of the monitor 10 preferably are powered by electrical energy induced in the monitor 10 from a source outside the body. An antenna coil 28 is wound around a lower portion of the spherical monitor 10 to provide a means for inductively receiving energy from outside the body and providing a power source to the monitor 10. This placement allows communication external to the stent. A power regulator 30 is connected to the

coil 28 and supplies regulated DC power to the transducer 26 and other circuits of the monitor 10, including a processor 32 and a transmitter 34. The transmitter 34 generates an electromagnetic wave, which is preferably in the radio-frequency (RF) band. The RF transmitter 34 may employ the stent 14 which is metallic, and acts as an antenna, requiring an interconnection therewith. In the embodiment of FIGURE 2, this is facilitated by a connection 36 from the transmitter 34 to the stent 14 passing through the socket 20.

Referring now to FIGURE 3, there is illustrated a block diagram of a monitoring system, according to a disclosed embodiment. A dashed line 38 separates the monitor 10 on the right side, as deployed within the patient's body, from a station 40 on the left side, located outside the patient's body. The station 40 includes a central processing unit (CPU) 42 that is in communication with and controls a power transmitter 44, a radio-frequency receiver 46, and a display panel 47.

When the station 40 is in proximity to the patient's body so that it can communicate with the monitor 10, the CPU 42 initiates an inquiry to the monitor 10 by powering up the power transmitter 44. The power transmitter 44 directs low frequency electromagnetic radiation 48 at the patient's body and monitor 10 therein. The varying magnetic field component of the electromagnetic radiation 48 induces a current in the power coil 28. The power regulator 30 then converts the AC current induced in the power coil 28 to DC current, which is then regulated to provide a relatively constant voltage level of, e.g., three volts to the other circuits of the monitor 10 including the processor 32, transducer 26, and RF transmitter 34.

Once energized in the aforementioned manner, the monitor 10 can sense a quantitative condition of the blood flowing through the stent 14. Specifically, in this example, the monitor 10 can sample blood pressure and convert the blood pressure value to electrical signals by means of the transducer 26. However, other aspects of the blood such as temperature, opacity, etc. could also be sensed with the appropriate sensor. The processor 32 then preferably converts the electrical signals from the transducer 26 into digital data for accurate transmission out to the station 40. The digital data signals representing the pressure parameter are modulated onto a carrier frequency signal by the RF transmitter 34 and transmitted by radio waves 50 outside the body for reception by the RF receiver 46. The CPU 42 then demodulates the RF carrier frequency signal to extract the pressure parameter data and stores the data in a computer memory

(not shown). The CPU 42 can also report the pressure data to the patient or a technician by means of the display panel 47.

Systems that energize and interrogate remote electronic devices using electromagnetic energy and RF communication are well known. Such remote electronic devices are sometimes referred to as passive transponders. Examples are described in U.S. Patent Nos. 4,345,253, entitled "Passive Sensing and Encoding Transponder," issued August 17, 1982; 4,857,893, entitled "Single Chip Transponder Device," issued August 15, 1989; 5,252,962, entitled "System Monitoring Programmable Implantable Transponder," issued October 12, 1993; and 5,347,263, entitled "Electronic Identifier Apparatus and Method Utilizing a Single Chip Microcontroller and an Antenna Coil," issued September 13, 1994, which are hereby incorporated by reference.

As an alternative to using separate coils for the antenna coil 28 and RF transmitter 34, a single antenna coil could be used. This alternative of a dual-purpose coil is described in commonly-assigned U.S. Patent Application entitled "Miniature Spherical-Shaped Semiconductor With Transducer," which is hereby incorporated by reference, and which was filed on the same date of the present application.

Referring now to FIGURE 4A, there are illustrated additional details of the monitor 10. The monitor 10 is hermetically protected by a thin exterior glass passivation layer 52, which may be phosphosilicate glass (PSG). The interior of the ball monitor 10 comprises a semiconductor substrate 54, which may be doped p-type or n-type in accordance with the particular requirements of the fabrication process. Optionally, the substrate 54 may be connected to the stent 14 or other metallic intraluminal device to serve as a ground potential for the monitor 10. The transducer 26 has an outer surface 56 that is exposed to the bloodstream flowing through the patient's artery (or to any other application which interfaces with fluids flowing in a body lumen). The transducer 26 preferably is formed atop a thick dielectric layer 58, which may be a field oxide layer grown on the substrate 54.

A large number of transistors make up the circuitry of the power regulator 30, processor 32 and RF transmitter 34, described above in connection with FIGURES 2 and 3. Some of these transistors are depicted in FIGURE 4A, and labeled with the letter "T." Although these transistors T are schematically depicted as MOS transistors, the integrated circuitry of the

monitor 10 could also use bipolar transistors. The individual transistors T are shown separated by portions of the field oxide 58. Transistor gates G and circuit interconnections (not shown) are embedded in an interlevel dielectric layer 60 and are made using conventional semiconductor fabrication techniques adapted to the spherical surface of the monitor 10.

The antenna coil 28 described in connection with FIGURES 2 and 3 is shown as having a plurality of separate windings 62a, 62b, 62c and 62d, which may be fabricated from a deposited layer of aluminum (or copper) that is patterned and etched using conventional semiconductor fabrication techniques adapted to the spherical shape of the monitor 10. The windings are insulated from each other by portions of the interlevel dielectric layer 60. The actual number of individual windings of the coil may be far greater than the four specific windings shown. The ends of the coil 28 are connected by additional conductors (not shown) to other circuit elements of the monitor 10.

Referring now to FIGURE 4B, there is illustrated an implementation of the transducer 26. By way of example, the transducer 26 may consist of a strain gauge fabricated atop the field oxide 58. A dome 63 is supported at its periphery by the field oxide 58 and defines a cavity 65 between the dome and the field oxide 58. The dome 63 preferably comprises monocrystalline silicon and includes an elongated doped resistor 67, which is indicated by the stippling at the outer surface of the silicon dome 63. A dielectric layer 69, such as silicon dioxide, overlies the dome 63. Metal contacts 71 and 73 are formed atop the dielectric layer 69 and extend therethrough to make contact with the opposite ends of the doped resistor 67. The metal contacts 71 and 73 have extensions (not shown in the cross section) that interconnect the resistor with circuitry of the previously described processor 32.

The strain gauge transducer 26 can be fabricated by forming a layer of selectively etchable material in the shape of the cavity 65 over the field oxide layer 58. For example, a phosphorus doped oxide can be deposited on the surface of the device, and then patterned into the desired shape by photolithographic techniques adapted to the spherical shape of the device. Next, the silicon dome 63 is formed, such as by the deposition of polycrystalline silicon followed by recrystallization. Alternatively, the monocrystalline silicon layer used to make the dome 63 can be epitaxially grown, such as by seeding the growth from an exposed portion of the substrate 54 adjacent to the field oxide 58. Such techniques are known, as described in U.S. Patent No.

4,754,314, entitled "Split-Level CMOS," issued June 28, 1988. A patterning procedure is then used to define the ultimate shape of the periphery of the dome 63. Then, peripheral ports (not shown) are etched at opposite sides of the dome 63 down to the doped oxide layer. Next, the device is exposed to an acid that preferentially etches doped oxide at a much faster rate than undoped silicon dioxide. It is well known that hydrofluoric acid will etch phosphorus doped oxide at a much faster rate (e.g., 15 times faster) depending on the phosphorus doping level and oxide density. The acid flows into the peripheral ports and etches the doped oxide layer laterally beneath the silicon dome 63 to create the cavity 65. The acid is then flushed out to introduce air or other gas, such as nitrogen, into the cavity 65. Then, the outer dielectric layer 69 is formed followed by the contacts 71 and 73. The deposition of the silicon dioxide of the dielectric layer 69 fills the peripheral ports and seals the cavity 65.

In a variation of the foregoing technique, a thin silicon nitride layer (not shown) can be deposited on the field oxide layer 58 to serve as an etch-stop layer, followed by the deposition and patterning of the selectively etchable oxide layer. Optionally, another thin silicon nitride layer can be deposited atop the patterned oxide layer prior to the formation of the silicon layer 63. These additional steps can facilitate preferential lateral etching of the patterned oxide layer to create a cavity like the cavity 65, since hydrofluoric acid etches oxide at a much faster rate (e.g., 50 times faster) than silicon nitride.

In operation, the strain gauge 26 senses pressure applied to the dome 63 through the dielectric layers 52 and 69. As the pressure increases, the dome 63 flexes downward very slightly, which also compresses the gas in the cavity 65 to a slight degree. The resistance of the resistor 67 varies in proportion to the variations in pressure of the fluid adjacent the outer surface 56 of the dielectric layer 52. The characteristics of semiconductor strain gauges are known in the art. A semiconductor strain gauge whose essential characteristics are similar to the strain gauge 26 of FIGURE 4B is described in U.S. Patent No. 4,618,844, entitled "Semiconductor Pressure Transducer," issued October 21, 1986, which is hereby incorporated by reference

Other techniques may be used to integrate a pressure transducer onto the surface of a semiconductor ball. For example, variable capacitors, which are ideally suited for sensing pressure, can be fabricated using conventional semiconductor fabrication processes. A method of making a variable capacitor semiconductor transducer is described in U.S. Patent No. 4,665,610,

entitled "Method of Making a Semiconductor Transducer Having Multiple Level Diaphragm Structure," issued May 19, 1987, which is hereby incorporated by reference. Such a method or variations thereof can be adapted for fabrication on a spherical-shaped semiconductor substrate.

Referring now to FIGURE 4C, there is illustrated a conventional strain gauge circuit according to the device structure of FIGURE 4B. A conventional strain gauge architecture comprises a set of four resistances in the configuration of a Wheatstone bridge. Resistances R1, R2, R3 and R4 are connected end to end in a loop such that the output signals are extracted from opposing nodes 200 (a node common to resistances R1 and R2) and node 202 (a node common to resistances R3 and R4). In like fashion, the excitation voltage is applied at the remaining two opposing nodes 204 (the point common between resistances R1 and R4) and node 206 (the point common to resistances R2 and R3). The excitation voltage is supplied by a power source 208 placed across the nodes 204 and 206. In the context of FIGURE 4B, the consolidation of resistances R1, R2, R3 and R4 represent the elongated doped resistor 67 illustrated in FIGURE 4B. The elongated doped resistor 67 may be tapped off at various points to obtain the illustrated Wheatstone bridge. The metal contacts 71 and 73 of FIGURE 4B relate to the output terminals 210 and 212 which interface with the processor 32. The power source 208 may comprise a miniature self-contained battery system, as described hereinbelow, or may be provided externally from location 40 coupled into the monitor 10 through antenna 28 and provided through power regulator 30 to the strain gauge transducer 26. When under strain, the elongated doped resistor 67 flexes such that resistance values R1, R2, R3 and R4 are changed in proportion to the changing condition sensed. The output at nodes 210 and 212 is a voltage which varies in direct relationship to the parameter being measured by the strain gauge transducer 26.

Referring now to FIGURE 5, there is illustrated a portion of a monitor 10', as modified from the embodiment of FIGURE 4A using similar reference numerals which designate similar elements. The monitor 10' includes a substrate 54' on which a thick field oxide 58' has been grown. Overlying the thick field oxide 58' is a pressure transducer 26' whose outer surface has been modified in accordance with a disclosed embodiment. The portion of dielectric layer 52' lying over the transducer 26' has recesses 64 formed in its outer surface. These recesses 64 may also extend beyond the edges of the transducer 26' at least so far as the monitor's surfaces may be exposed to the bloodstream.

The purpose of the recesses 64 is to inhibit tissue adhesion to the surfaces of the monitor 10' that are exposed to the patient's blood. Tissue adhesion is known to occur on the surfaces of implants through the attachment of fibroblasts. This phenomenon is well known and is described in Von Recum et al., "Surface Roughness, Porosity, and Texture as Modifiers of Cellular Adhesion," *Tissue Engineering*, Vol. 2, No. 4, 1996 (available from the Dept. of Bioengineering, Clemson University, Clemson, SC). The recesses 64 are presently preferred to be about 1 micron deep, 3 microns wide, and spaced 3 microns apart in a checkerboard topography. Such recesses can be fabricated by conventional selective etching techniques adapted to the spherical shape of the monitor 10.

Referring now to FIGURE 6A, there is illustrated an alternative embodiment of an intraluminal monitoring system. A stent 68 includes two semiconductor balls 70 and 72 juxtaposed on opposite sides of the stent. The stent 68 may be made of a conventional woven metal such as NiTi like the stent 14 previously described, which is suitable for use in an artery (not shown) and implanted therein by conventional balloon angioplasty or other intravascular delivery system. The balls 70 and 72 preferably are embedded in the stent wall 68a in a manner similar to that used to anchor the ball monitor 10 in the stent 14 of FIGURE 2.

The ball 70 is a semiconductor device that includes a light emitting diode (LED) on one surface oriented in the wall 68a such that it emits a light beam 74 of a generally conical shape into the interior of the stent 68. The light beam 74 is directed so that it impinges on a surface 76 of the ball 72 within the interior of the stent 68. Just beneath the surface 76, which includes a protective coating (not shown) such as phosphosilicate glass, is a photodiode (not shown). The photodiode converts the intensity variations of the light beam 74 into electrical signals from which the flow rate of blood passing through the stent 68 can be computed. The electrical signals produced by the photodiode or a computed value of flow rate can be transmitted to a station outside the patient's body in a manner similar to the technique described above in connection with FIGURE 3. It should be understood that a frequency of emission can be utilized, such as x-ray, etc.

The intraluminal monitoring system can also be applied in a similar manner to stents placed in locations of post-inflammatory strictures, which may develop within the tracheobronchial tree, pancreatic-biliary duct system, gastrointestinal system (e.g., esophagus,

pylorus, small and large intestine), and urological system (e.g., ureter, urethra and prostate). It will also be appreciated that the disclosed embodiment can have applications that are purely for monitoring purposes rather than the treatment of a pathological condition. For example, an intraluminal device, such as stent or small graft, that includes a miniature monitor as described herein can be implanted at a site where the monitoring function is required. A catheter delivery system can be used for this purpose, and if need be adapted to securing the intraluminal device at a selected site in a healthy vessel or luminal system.

Referring now to FIGURE 6B, there is illustrated an LED/photodiode pair in operation according to the embodiment of FIGURE 6A, and depicting the device structures for use according to the embodiment of FIGURE 4A. The light emitting diode ball 70 emits light 220 (or other energy) across the luminal region of the stent 68 to a light detecting ball 72. It is desirable that the balls 70 and 72 should be installed substantially perpendicular to the radial axis of the stent, and aligned with one another in opposite ends of a diametrical line of the stent 68 such that the direction of light 221 emitted from the emitter ball 70 impinges a photodiode 222 (or other receptor) of the detector ball 72 in a direction which is substantially perpendicular to the flow 223 of the fluid being measured. The light emitting diode structure 220 of the emitter ball 70 emits light which is dispersed across an area sufficient for the photodiode structure 222 of the light detecting ball 72 to detect. Each ball 70 and 72 is sealed with a thin exterior glass passivation layer 52 (e.g., PSG) to provide isolation of the ball electronics from the body tissues and fluids being measured.

The detector structure 222 of ball 72 is commonly known, and can be conformed to the arcuate surface of the ball 72 using conventional deposition and fabrication technique practices. For example, underlying the passivation layer 52 are metal contacts 224 for electrical interfacing. Underlying the metal contacts 224 is an oxidation layer 226 (e.g., SiO_2). The metal contacts 224 contact a diffused region 228, which may be a p^+ region, in this particular embodiment. Underlying the p^+-doped region 228 lies a n-doped region 229, followed by the substrate 54, which may a more heavily doped n^+ region.

The LED structure 220 of emitter ball 70 is also commonly known, and a wide variety of structures may be employed to obtain the desired results. For example, underlying the glass passivation layer 52 are metal contacts 230 which contact a diffused region 232. The diffused

region 232 may be a p^+-region diffused in an n-type region 234 which overlies the more heavily n^+-doped substrate 54. Note that the photo structures are not limited to diodes, but may also be phototransistor structures.

Referring now to FIGURE 6C, there is illustrated a conventional circuit diagram of the LED/photodiode circuit as fabricated and illustrated in FIGURE 6B. As mentioned hereinabove, the middle ball 70 comprises the LED 240, which LED 220 interfaces to emitter interface electronics 240. In operation, the emitter interface electronics 240 drives the LED 220 to emit light 221 which impinges on a photocoupler 222 fabricated into the photo detector ball 72. The photocoupler 222 outputs a voltage in proportion to the light intensity of the source LED 220, which voltage signals are fed into coupler interface electronics 242 of the detector ball 72. As mentioned hereinabove, the light 221 is emitted from LED 220 across the lumen having blood flowing therethrough.

Referring now to FIGURE 7, there is illustrated another alternative embodiment of an intraluminal monitoring system. A stent 78 includes a monitor 80 consisting of three balls 81, 82 and 83 interconnected through contacts, which contacts are described in greater detail hereinbelow. The ball 81 includes a self-contained DC power source (not shown), such as a miniature battery that is constructed of non-toxic materials. The ball 82 includes a miniature radar system that transmits radio waves 84 at an angle of about 45 degrees to the longitudinal axis of the stent 78. The ball 82 detects the reflections from blood cells flowing in the bloodstream, as indicated by the arrows 86. Instantaneous measurements of the bloodstream velocity can thus be measured. The ball 83 includes a semiconductor memory (not shown) that stores periodic samples of discrete time blocks of bloodstream velocity. The ball 83 also includes a receiver/transmitter for communicating with an external monitoring station as described above in connection with FIGURE 3. When the patient comes within range of the monitoring system, ball 83 receives an inquiry signal, and then transmits a complete record of bloodstream velocity data from its memory out to the monitoring station.

In a further variation, a monitor having two balls may be placed near opposite ends of an intraluminal device, one ball serving as an ultrasound transmitter and the other as a receiver. Calculation of flow rate can be made according to the well-known Doppler effect. Alternatively, placing the transmitter and receiver balls on opposite sides of an intraluminal device can allow

measurement of the effective diameter by measuring the time of flight of a generated wave. A reduction of the effective diameter over time can thereby be monitored.

Referring now to FIGURE 8, there is illustrated a side elevation of a cluster of semiconductor balls that may be employed in a transducer function. Although a single ball can include the foregoing functions, more complex monitoring functions with multiple transducers can be implemented using multiple ball systems attached to catheters, needles and other insertable devices. For example, ball 81 can include power receiving and data transmission functions. Alternatively, ball 81 can be a miniature ball-shaped battery. Ball 82 can include a first transducer function, such as pressure sensing, and ball 83 can include a second transducer function, such as measuring pH, pO_2, pCO_2, or temperature, as the particular application requires. Connections between the balls are made through metal contacts 90, which may be solder bumps, and as described in greater detail hereinbelow, the metal contacts 90 may be used for a variety interface functions, such as power, data, and a signal bypass path.

Referring now to FIGURE 9, there is illustrated a cross section along the line 9-9 of FIGURE 8 to expose four contacts 88a, 88b, 88c and 88d between ball 82 and ball 83. As mentioned hereinabove, the contacts may be employed to interface a variety of functions, for example, the contacts 88a and 88b may be power contacts, such as a positive 3.0 volts and ground, which can be passed from ball 81 around ball 82 by conductors on its surface using two of a group of similar contacts (designated collectively by numeral 90 in FIGURE 8). The contacts 88c and 88d may be data and control contacts for communications between ball 82 and ball 83. Similar data and control contacts may exist among contact group 90 between ball 81 and ball 82 to the extent needed.

Referring now to FIGURE 10, there is illustrated a cluster of balls 91, 92, 93, 94, 95 and 96 as an example of the versatility of such ball systems. The cluster specifically shows six balls arranged in a three-dimensional configuration. It will be appreciated that various other cluster arrangements are possible, limited only by the constraints of the end-use application. Each of the balls of the cluster can perform different electronic functions and communicate with each other through contacts as described above in connection with FIGUREs 8 and 9. Such cluster

arrangements are not limited to the previously described stent applications, but may also have applications in other intraluminal monitoring systems, including those described hereinbelow.

GRAFT MONITORING APPLICATIONS

Referring now to FIGURE 11, there are illustrated monitors 110a and 110b embedded in the walls of a graft 112, which has been implanted in an abdominal aortic aneurysm 114. The graft 112 may be a woven fabric or a fabric with a metal mesh included, both variations being well known, the latter sometimes being referred to as a stent-graft. Procedures for implanting the graft 112 are well known and need not be described in detail herein. Briefly, access to the site of the aneurysm 114 is made by a catheter delivery system (not shown) inserted into a femoral artery and then up through the adjoining iliac artery. The result of the graft implant procedure is the permanent inclusion of the graft 112 extending from a point just below the renal arteries 116R and 116L to a point just above the iliac arteries 118R and 118L. The purpose of the graft 112 is to relieve the pressure on the weakened walls of the aneurysm 114. The graft 112 is endosurgically stitched to the aorta at its upper and lower ends to create seals, which are designated 118 at the upper end and 120 at the lower end of the graft 112.

The seals 118 and 120 prevent blood flow through the space between the graft 112 and the aortic walls that had defined the aneurysm 114. Leakage of blood through this space can indicate a partial detachment of the graft 112 from the aorta at the seals 118 and 120. Also, clotting can occur within the lumen of the graft, particularly in the areas of the seals 118 and 120. The monitors 110a and 110b are provided to detect the occurrence of such conditions. In particular, monitor 110a can be a spherical semiconductor monitor similar to the monitor 10 described above in connection with FIGURE 2. Thus, the monitor 110a can detect pressure within the lumen of the graft 112. Alternatively, the monitor 110a could be replaced by a monitor pair as described above in connection with FIGURE 6A to permit the detection of flow rate through the graft 112. Similarly, the monitor 110b could be of the type described in connection with FIGURE 2 to detect pressure, but in this case, the pressure of interest would be in the space between the graft 112 and the aneurysm wall 114. Therefore, the pressure-sensitive surface of the monitor 110b would face outward into the space between the graft 112 and the aneurysm wall 114. Several such monitors 110b could be located at different points around the graft 112 to detect pressure differentials, which would be indicative of leakage of blood flow around the graft 112.

It will be appreciated that grafts 112 having bifurcated ends extending down into the iliac arteries, are also well known and suitable for use in the disclosed system. The disclosed architecture is equally applicable with grafts 112 implanted above the renal arteries to repair thoracic aortic aneurisms.

Another application for the disclosed intraluminal monitoring system is the inclusion of a monitor (or monitors) on a vena cava filter. Such filters and their use in the treatment of thromboembolic diseases are well known, an example being the Greenfield vena cava filter. A monitor secured to such a filter can provide vital patency information over time.

A-V FISTULA MONITORING APPLICATIONS

Referring now to FIGURE 12, there is illustrated the intraluminal monitoring system as applied in an arteriovenous (A-V) fistula, such as are used for kidney dialysis patients to facilitate connection to a dialysis machine. A diagram showing the interior of a patient's arm 122 reveals an A-V fistula 124 interconnecting an artery 126 and a vein 128. The material of the A-V fistula 124 is a suitable plastic such as polyethylene. When performing dialysis, the patient's blood is withdrawn through a first needle (not shown) inserted through the skin into the lumen of the A-V fistula near the artery 126. Blood is returned from the dialysis machine through a second needle (not shown) inserted through the skin into the lumen of the A-V fistula near the vein 128. In the event of stricture development or narrowing near or within the A-V fistula 124, the disclosed architecture can provide a means of detection so that corrective treatment can be performed.

Referring now to FIGURE 13, there is illustrated a cross section of the A-V fistula 124 at a location that includes monitor elements 130 and 132. A system similar to that described above in connection with FIGURE 6A can be employed to detect flow rate, in which case element 130 includes an LED at its inwardly facing surface 134. A light beam 136 from the LED of monitor element 130 is directed at the inwardly facing surface 138 of the monitoring element 132. Just below surface 138 is a photodiode (not shown), which detects intensity variations that relate to flow rate, as described hereinabove. Alternatively, a pressure sensor monitor can be employed, as described above in the context of FIGURE 2. The monitor 132 may serve this purpose, as well as sensing light intensity such that a multi-function monitor 10 containing two or more transducers may be employed to measure two or more respective quantitative conditions.

Parameters indicative of flow rate through the A-V fistula 124 and/or pressure at points therein can be communicated to a station outside the body, in the manner described above in connection with FIGURE 3. If pressure data is employed, it is preferable to collect the pressure data at three points, as indicated by the section lines A-A, B-B and C-C, in FIGURE 12. Using such pressure data, the location of a stenosis can be determined early and corrected, thus preventing further complications and avoiding more extensive surgical procedures at a later time. For example, a drop in pressure from line B-B to line C-C would indicate the existence of a narrowing of the lumen between those two points.

It will be appreciated that the foregoing devices operate in a novel manner made possible by the miniaturization of the electrical components and unique implementation in a living body. The method of operation described above in connection with FIGURE 3 can be adapted to any of the implanted monitors described herein and variations thereof that suggest themselves to the skilled pracitioner, including uses of such monitors in livestock and other animals. The parameters sensed and transmitted outside the body are not limited to pressure and flow rate in a vessel, but can include, by way of example, temperature and levels of pH, O_2, alcohol, etc., in the bloodstream. The parameters desired to be measured may be made in living tissue or tissue which is not living.

Referring now to FIGURE 14, there is illustrated a schematic block diagram of the monitor and the remote system for the powering/detection operation. The monitor 10, as described hereinabove, is operable to provide a transducer 26 for interfacing with the desired quantitive condition. The illustrated embodiment of FIGURE 14 is that associated with a "passive" system, which term refers to a system having no battery associated therewith. In order to operate the system, there is provided an inductive coupling element 1404 in the form of an inductor, which is operable to pick up an alternating wave or impulse via inductive coupling, and extract the energy therein for storage in the inductive element 1404. This will create a voltage across the inductive element 1404 between a node 1406 and a node 1408. A diode 1410 is connected between the node 1408 and the node 1412, with the anode of diode 1410 connected to node 1408 and the cathode of diode 1410 connected to a node 1412. Typically, the diode 1410 will be fabricated as a Schottky diode, but can be a simple PN semiconductor diode. For the purposes of this embodiment, the PN diode will be described, although it should be understood that a Schottky diode could easily be fabricated to replace this diode. The reason for utilizing a

Schottky diode is that the Schottky diode has a lower voltage drop in the forward conducting direction.

The diode 1410 is operable to rectify the voltage across the inductive element 1404 onto the node 1412, which has a capacitor 1414 disposed between node 1412 and node 1406. Node 1412 is also connected through a diode 1416 having the anode thereof connected to node 1412 and the cathode thereof connected to a node 1418 to charge up a capacitor 1420 disposed between node 1418 and 1406. The capacitor 1420 is the power supply capacitor for providing power to the monitor 10. The capacitor 1414, as will be described hereinbelow, is operable to be discharged during operation of the system and, therefore, a separate capacitor, the capacitor 1420, is required for storing power to power the system of the monitor 10.

There is also provided a switching transistor 1431 which has one side of the gate/source path thereof connected to a node 1428 which is the output of the transducer 26 and the other side thereof connected to a node 1432. The gate of transistor 1431 is connected to the output of the switch control 1430. Node 1432 is connected to the input of a buffer 1434 to generate an analog signal output thereof which is then converted with an analog-to-digital converter 1436 to a digital value for input to a CPU 1438. The CPU 1438 is operable to receive and process this digital input voltage. A clock circuit 1440 is provided for providing timing to the system. A memory 1439 is provided in communication with the CPU 1438 to allow the CPU 1438 to store data therein for later transmittal back to the remote location or for even storing received instructions. This memory 1439 can be volatile or it can be non-volatile, such as a ROM. For the volatile configuration, of course, this will lose all information when the power is removed. The CPU 1438 is operable to provide control signals to the switch control 1430 for turning on the transistor 1431 at the appropriate time. In addition to the transistor 1431 being toggled to read the transducer 26, transistor 1431 could be a pass-through circuit such that the CPU 1438 can continually monitor the voltage at the output of the transducer 26. System power to all power-consuming elements of the monitor 10 is provided at the SYSTEM PWR output node.

In order to communicate with the CPU 1438 for transferring data thereto and for allowing the CPU 1438 to transfer data therefrom, a receive/transmit circuit 1442 is provided for interfacing to node 1412 through a resistive element 1444. This allows RF energy to be transmitted to node 1412. It is important to note that the semiconductor junction across diode

1410 is a capacitive junction. Therefore, this will allow coupling from node 1412 to node 1408. Although not illustrated, this could actually be a tuned circuit, by selecting the value of the capacitance inherent in the design of the diode 1410. In any event, this allows an RF connection to be provided across diode 1410 while allowing sufficient energy to be input across conductive element 1404 to provide a voltage thereacross for rectification by the diode 1410 and capacitor 1414. Typically, the frequency of this connection will be in the MHz range, depending upon the design. However, many designs could be utilized. Some of these are illustrated in Beigel, U.S. Patent No. 4,333,072, entitled "Identification Device," issued June 1, 1982, and Mogi et. al, U.S. Patent No. 3,944,982, entitled "Remote Control System For Electric Apparatus," issued March 16, 1976, which are incorporated herein by reference. With these types of systems, power can continually be provided to the node 1412 and subsequently to capacitor 1420 to allow power to be constantly applied to the monitor 10.

The remote system 40 which is disposed outside of the body and proximate to the monitor 10 includes an inductive element 1450 which is operable to be disposed in an area proximate to the skin, yet exterior to the body, in the proximity of the monitor 10, as close thereto as possible. The inductive element 1450 is driven by a driving circuit 1452 which provides a differential output that is driven by an oscillator 1454. This will be at a predetermined frequency and power level necessary to couple energy from inductive element 1450 to inductive element 1404. Since this is an external system, the power of the oscillator can be set to a level to account for any losses through the body tissues. To allow information to be transmitted, a modulation circuit 1456 is provided which is modulated by a transmitter signal in a block 1458 that allows information to be modulated onto the oscillator signal of the oscillator 1454, which oscillator signal is essentially a "carrier" signal. However, it should be understood that the information that is transmitted to the monitor 10 could merely be date information, whereas the CPU 1438 could operate independent of any transmitted information to provide the correct timing for the output pulses and the correct waveshape therefor. Alternatively, entire control of the system could be provided by the transmit signal 1458 and the information carried thereon, since power must be delivered to the illustrated embodiment due to the lack of any independent power in the monitor 10.

When the information is received from the monitor 10, it is superimposed upon the oscillator signal driving the inductive element 1450. This is extracted therefrom via a detector

1460 which has the output thereof input to a first low pass filter 1462, and then to a second low pass filter 1464. The output of low pass filters 1462 and 1464 are compared using a comparator 1466 to provide the data. The filter 1462 provides an average voltage output, whereas the filter 1464 provides the actual digital voltage output. The output of the comparator 1466 is then input to a CPU 1470 which also is powered by the oscillator 1454 to process the data received therefrom. This can then be input to a display 1472.

Referring now to FIGUREs 15A-15C, there are illustrated alternate embodiments for the transmit/receive operation. In FIGURE 15A, there is provided an oscillator 1500 which drives an external inductive element 1502. Typically, there is some type of load 1504 disposed across the inductive element 1502. This is the primary power that is provided to the system. A separate inductive element 1506 is provided on the monitor 10, for being inductively coupled to the inductive element 1502. Thereafter, a voltage is generated across the inductive element 1506, the inductive element 1506 being connected between nodes 1508 and 1510. A diode 1512 is connected between node 1508 and a power node 1514, and a power supply capacitor 1516 is disposed across node 1514 and a node 1510. This allows the voltage on node 1508 to be rectified with diode 1512.

In FIGURE 15B, the receive operation, in this alternative embodiment, utilizes a separate inductive element or antenna 1524 in the monitor 10, which is operable to be connected between nodes 1509 and 1511. Node 1509 is capacitively coupled to a transmit node 1530 with a capacitor 1532, the capacitor 1532 being a coupling capacitor. A transmitter 1534 is provided for transmitting received data from a line 1536 to the node 1530, which is then coupled to the node 1509 to impress the RF signal across the inductive element 1524.

A corresponding inductive element 1540 is disposed on the external remote controller of remote location 40, which inductive element 1540 is operable to be disposed proximate to the inductive element 1524, but external to the human body. The inductive element 1540 is basically a "pick-up" element which is operable to receive information and function as an antenna, and provide the received signal to a receiver 1542. The structure of FIGURE 15B is a separate structure, such that node 1509 is isolated from node 1508, the power receiving node. However, it should be understood that any harmonics of the oscillator 1500 would, of course, leak over into the inductive element 1524. This can be tuned out with the use of some type of tuning element

1544 on the monitor 10 disposed across inductive element 1524, and also a tuning element 1546 disposed across the inductive element 1540, i.e., the antenna.

Referring now to FIGURE 15C, there is illustrated a simplified schematic diagram of the receive portion. The monitor 10 has associated therewith a separate receive antenna or inductive element 1550 disposed between node 1513 and a node 1552. Node 1552 is capacitively coupled to a receive node 1554 with a coupling capacitor 1556. A receiver 1558 is provided for receiving the information transmitted thereto and providing on the output thereof data on a data line 1560. The receiver 1558 is operable to receive the RF signal, demodulate the data therefrom, and provide digital data on the output 1560. External to the human body and the monitor 10 is a transmitter 1562 which is operable to impress a signal across an external inductive element 1564. The inductive element 1564 basically provides the RF energy and is essentially tuned with a tuning element 1566. A corresponding tuning element 1568 is provided on the monitor 10 and disposed across inductive element 1550, the inductive element 1550 acting as an antenna, as well as the inductive element 1564.

Note that in circumstances where the signals of monitor 10 cannot be adequately received therefrom and/or power coupled thereto, the external location circuitry 40 may need to be inserted into the body proximate to the monitor 10 in order to couple the transmit/receive signals and power. Furthermore, where more than one monitor ball 10 is used, communication of power and data signals between the various monitors 10 may need to employ distinct time periods (i.e., time multiplexing) when communication occurs using a single common frequency, or discrimination circuits may need to be used where communication occurs simultaneously with the plurality of implanted monitors 10 having different oscillator frequencies.

Referring now to FIGURE 16, there is illustrated a side view of an alternative embodiment utilizing additional circuitry or structure attached to the monitor 10 for providing a local power source. As described hereinabove, the monitor 10 requires a power-generating structure for storing a power supply voltage such that diodes must be provided for receiving and rectifying a large amount of power and charging up a power supply capacitor. Alternatively, the monitor 10 could be configured to interface to an attached power supply system 1600 comprising either a battery or a capacitor. The local power supply system 1600 is illustrated as disposed on a circuit board 1603 defined by supporting structures 1602 and 1604. The circuit board 1603

contains electronics for interfacing the local power supply system 1600 to the monitor 10.

Referring now to FIGURE 17, there is illustrated a schematic block diagram of the monitor 10 using a battery as the local power supply system 1600. A battery 1701 is provided as a source of self-contained power and is connected across a capacitor 1700 to provide smoothing of any power output to the system power-consuming elements of the monitor 10. Power for all on-board components is obtained from the SYSTEM POWER output by providing sufficient charge to the capacitor 1700. The capacitor 1700 could be formed on the surface of the monitor 10 or it could actually be part of the battery structure 1701. Additionally, the capacitance 1700 could actually be the capacitance of the battery 1701. Additional structure could be provided for powering the CPU 1438 and the other circuitry on the monitor 10 from the battery 1701. As such, there would only be required a smaller inductive element 1702 and a capacitor 1704 to allow the receive/transmit block 1442 to receive/transmit information from and to the remote exterior station 40. The switch control 1430 controls the gate of the switching transistor 1431 to switch output of the transducer 26 through the switching transistor 1431 source/drain path to the CPU 1438. It should be understood that any inductive elements that are disposed on the monitor 10 need to be interfaced to the exterior of the stent to allow for a clear communication path external thereto.

Referring now to FIGURE 18, there is illustrated a perspective view of the monitor 10, wherein the inductive element 1404 (similar to inductive element 1702) is illustrated as being strips of conductive material wrapped around the exterior of the monitor 10. The inductive element 1404 is formed of a conductive strip wrapped many times around the monitor 10. The length of inductive element 1404 depends upon the receive characteristics that are required. As described hereinabove with reference to FIGUREs 15A-15C, there could be multiple conductive strips, each associated with a receive function, a transmit function or a power function, or they could all share one single conductive element or strip. Note that the inductive strips would be disposed on one side of the monitor 10 for communication purposes, as described hereinabove with reference to FIGURE 2.

On one end of the monitor 10 there is provided a transducer interface 1800 of the transducer 26 having, optionally, one or more interface balls 1802 (or partial balls, called nodules) associated therewith extending from the transducer interface surface to provide

enhanced engagement of the measuring surface or physical entity. The interface balls 1802 can be made of non-reactive material, e.g., gold to prevent degradation while in the body. Note that in some applications, the interface nodules 1802 are not required for obtaining the desired quantitative data. On the other end of the monitor 10 are provided interconnect balls 1804 (or nodules) for interconnecting to one or more other spherical balls, as described hereinabove, which may provide similar functions such as monitoring of quantitative data, or unique functions such as supplying only power or data buffering and storage.

Referring now to FIGURE 19, there is illustrated a cross-sectional diagram of the surface of the monitor 10 illustrating the conductive strips forming the inductive element 1404. The conductive strips are referred to by reference numeral 1910 which are spaced above the surface of the integrated circuit of the monitor 10 by a predetermined distance, and separated therefrom by a layer of silicon dioxide. A passivation layer 1911 is then disposed over the upper surface of the conductive strips 1910. The conductive strips 1910 can be fabricated from polycrystalline silicon but, it would be preferable to form them from the upper metal layer to result in a higher conductivity strip. This will allow the strips 1910 to be narrower and separated from each other by a larger distance. This separation would reduce the amount of capacitance therebetween.

One end of the strips 1910 is connected to a diode structure 1913. The diode structure 1913 is formed of an N-well implant region 1914 into which a P-well implant region 1916 is disposed, and an N-well implant region 1918 disposed within the P-well implant region 1916. This forms a PN diode where one end of the conductive strips 1910, a conductive connection 1920, is connected to the P-well 1916 implant region, and a conductive layer 1922 is connected at one end to the N-well implant region 1918. This conductive layer or strip 1922 extends outward to other circuitry on the integrated circuit and can actually form the capacitor. Since it needs to go to a capacitor directly, a lower plate 1924 formed of a layer of polycrystalline silicon or metal in a double-metal process, could be provided separated therefrom by a layer of oxide.

Although the preferred embodiment has been described in detail, it should be understood that various changes, substitutions and alterations can be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

WHAT IS CLAIMED IS:

1. A monitoring system for use in sensing a condition within a body and communicating with a station located outside the body, the system comprising:

an intraluminal device implanted within the body, the device having a wall defining a lumen; and

a miniature electronic monitor secured to the intraluminal device, the monitor having a transducer in communication with fluid adjacent the wall for sensing a quantitative condition of the fluid and generating an electrical signal corresponding to the sensed quantitative condition, the monitor having circuitry responsive to the electrical signal for generating an electromagnetic wave corresponding to the electrical signal for receipt by the station.

2. The monitoring system of Claim 1, wherein the miniature electronic monitor comprises a spherical-shaped semiconductor device on which the electromagnetic wave generating circuitry resides in the form of an integrated circuit.

3. The monitoring system of Claim 1, wherein the intraluminal device is a stent implanted at a site of a stenosis.

4. The monitoring system of Claim 3, wherein the stent serves as an antenna for radiating the electromagnetic wave.

5. The monitoring system of Claim 3, wherein the stent serves as an effective ground potential connection for the monitor.

6. The monitoring system of Claim 2, wherein the transducer comprises a strain gauge that is secured at the surface of the semiconductor device and is in electrical communication with the electromagnetic wave generating circuitry.

7. The monitoring system of Claim 6, wherein the strain gauge is configured to sense blood pressure.

8. The monitoring system of Claim 6, wherein the strain gauge has an array of

recesses on its outer surface to inhibit tissue adhesion.

9. The monitoring system of Claim 1, wherein the monitor includes means for generating power in response into a low frequency electromagnetic signal directed at the monitor by the station.

10. The monitoring system of Claim 9, wherein the electromagnetic wave generating circuitry comprises a processor and an RF transmitter, wherein the processor converts the electrical signal from the strain gauge to a data signal communicated to the RF transmitter, and the RF transmitter modulates the data signal onto a radio frequency carrier signal.

11. The monitoring system of Claim 10, further comprising a power transmitter located outside the body for generating the low frequency electromagnetic signal, and an RF receiver located outside the body that receives the RF signal transmitted by the monitor.

12. The monitoring system of Claim 1, wherein the intraluminal device is a graft implanted at a site of an aortic aneurysm.

13. The monitoring system of Claim 1, wherein the intraluminal device is an A-V fistula implanted in a patient's arm interconnecting an artery and a vein.

14. The monitoring system of Claim 1, wherein the intraluminal device is a graft connecting two vessel segments.

15. The monitoring system of Claim 1, wherein the intraluminal device is a graft connecting two arterial vascular segments.

16. The monitoring system of Claim 1, wherein the intraluminal device is a graft connecting two venous vascular segments.

17. The monitoring system of Claim 1, wherein the intraluminal device is a stent implanted in the tracheobronchial tree at a site of a stenosis.

18. The monitoring system of Claim 1, wherein the intraluminal device is a stent implanted in the pancreatic-biliary duct system at a site of a stenosis.

19. The monitoring system of Claim 1, wherein the intraluminal device is a stent implanted in the urological system at a site of a stenosis.

20. The monitoring system of Claim 1, wherein the intraluminal device is a vena cava filter.

21. The monitoring system of Claim 1, wherein the intraluminal device is a stent implanted in a gastrointestinal system.

22. The monitoring system of Claim 1, wherein the transducer detects the intensity of a light source directed through the interior of the intraluminal device, the monitor including circuitry for converting variations in the intensity of the light source to data indicating the flow rate of blood through the intraluminal device.

23. The monitoring system of Claim 1, wherein the transducer detects blood flow rate by directing high frequency waves into the bloodstream and detecting a frequency shift in the reflected waves.

24. The monitoring system of Claim 1, wherein the miniature electronic monitor comprises a cluster of spherical-shaped devices including a power source, a device containing the transducer, and an integrated circuit memory.

25. The monitoring system of Claim 24, wherein the spherical-shaped devices are interconnected by tangential contacts for transferring power, data, and control signals between the devices.

26. A method for monitoring a parameter of fluid flowing through an intraluminal device implanted within a living body, comprising:

energizing a monitor secured to the intraluminal device;

sensing quantitative data representing a parameter of fluid flowing through the intraluminal device;

converting the sensed data into electrical signals;

modulating the electrical signals onto a high frequency carrier signal;

transmitting the modulated carrier signal outside the body;

receiving the transmitted signal at a station outside the body;

demodulating the high frequency signal to extract a parameter computed from the quantitative data; and

displaying the parameter.

27. The method of Claim 26, wherein the energizing step is performed by directing low frequency electromagnetic radiation at the monitor from outside the body, and inducing a current in a coil on the monitor.

28. The combination comprising:

(a) a monitoring station having:

a central processing unit;

a power transmitter operating under the control of the central processing unit, the power transmitter being equipped to produce a low frequency electromagnetic field; and

a radio-frequency receiver operating under the control of the central processing unit;

(b) an intraluminal device implantable in a body; and

(c) a miniature electronic monitor affixed to the intraluminal device, the monitor having:

integrated circuitry including a processor;

a power coil responsive to the low frequency electromagnetic field to provide electrical energy to the monitor;

a transducer in communication with the processor for sensing a condition of the vascular system of the body; and

a radio-frequency transmitter in communication with the processor for transmitting a modulated signal including data representing the condition sensed by the transducer, the modulated signal being adapted to be received by the radio-frequency receiver of the monitoring station outside the body.

29. The combination of Claim 28, wherein the intraluminal device is configured for implantation at least partially within a body vessel.

30. The combination of Claim 28, wherein the monitor comprises at least one spherical-shaped semiconductor device.

31. The combination of Claim 28, wherein the monitoring station further comprises means for displaying the data representing the condition sensed by the transducer.

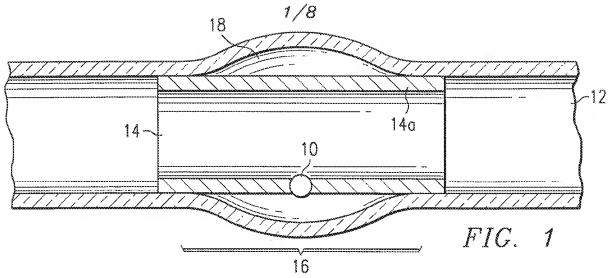


FIG. 1

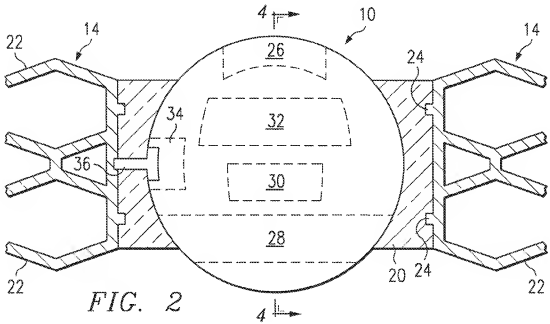


FIG. 2

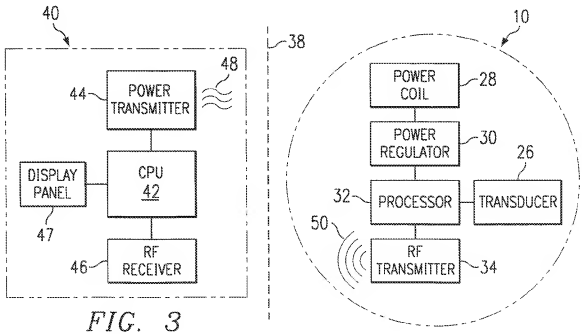


FIG. 3

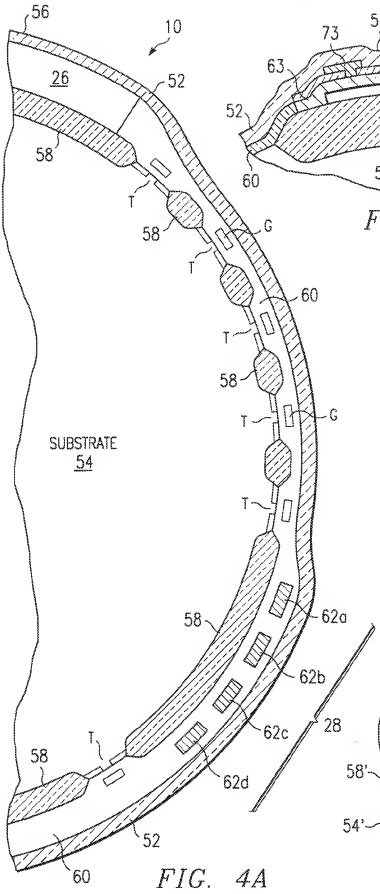


FIG. 4A

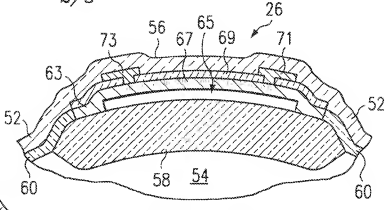


FIG. 4B

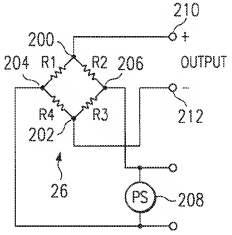


FIG. 4C

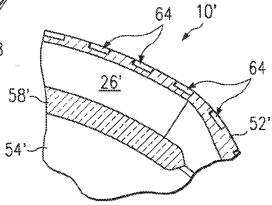


FIG. 5

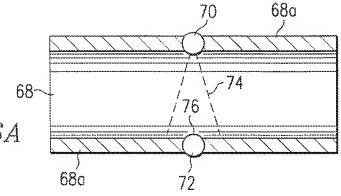


FIG. 6A

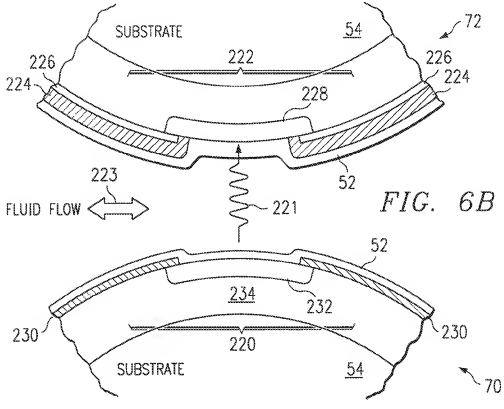


FIG. 6B

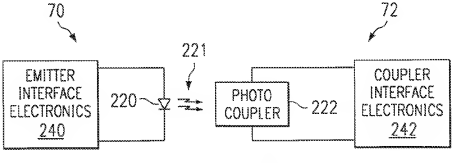


FIG. 6C

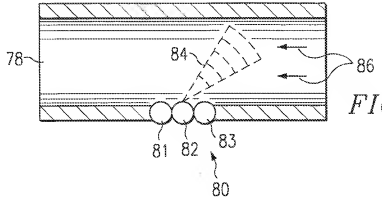


FIG. 7

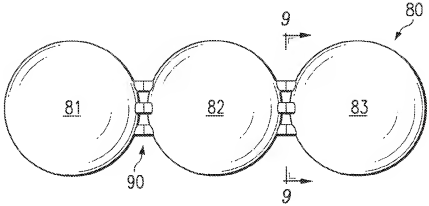


FIG. 8

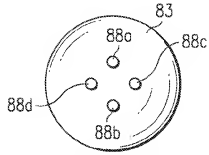


FIG. 9

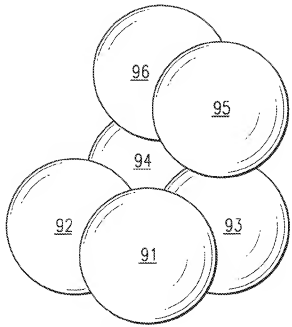
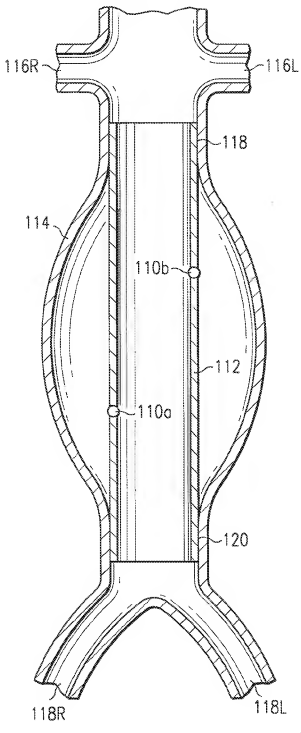


FIG. 10

FIG. 11



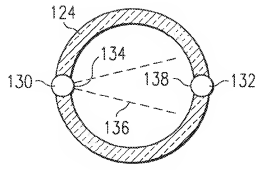


FIG. 13

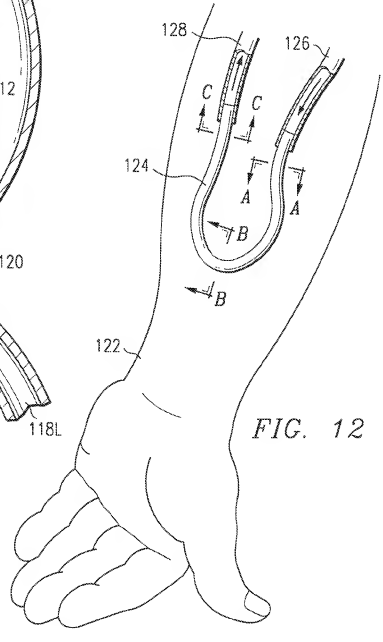


FIG. 12

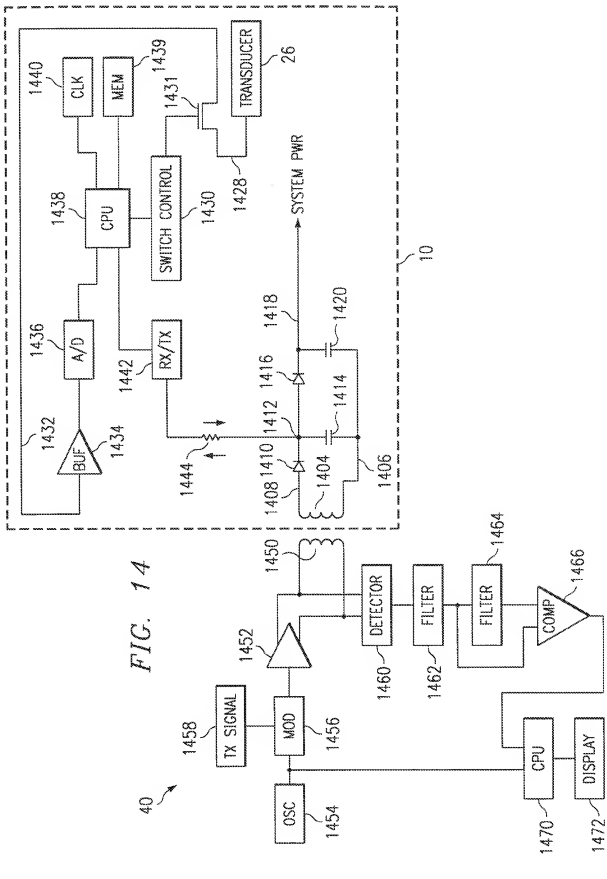

40
OSC
1454
TX SIGNAL
1458
MOD
1456
1452
1450
DETECTOR
1460
FILTER
1462
FILTER
1464
COMP
1466
CPU
1470
DISPLAY
1472
10
1444
1432
BUF
1434
1436
A/D
1442
RX/TX
1438
CPU
1440
CLK
MEM
1439
1431
SWITCH CONTROL
1430
1428
TRANSDUCER
26
SYSTEM PWR
1418
1420
1416
1414
1412
1410
1408
1404
1406

FIG. 14

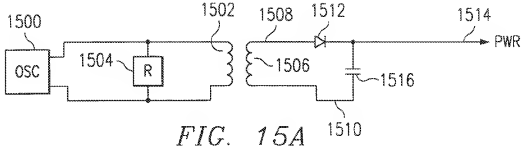


FIG. 15A

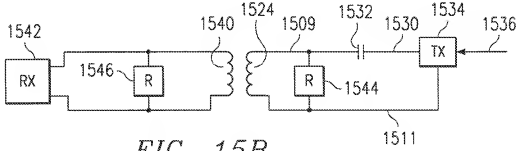


FIG. 15B

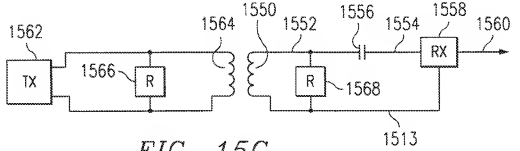


FIG. 15C

FIG. 16

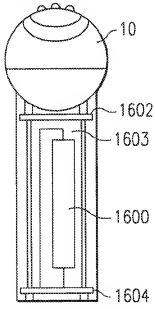


FIG. 17

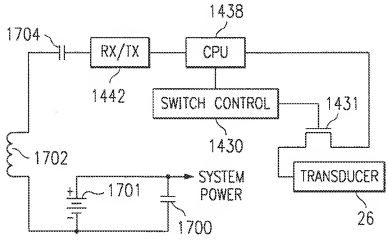


FIG. 18

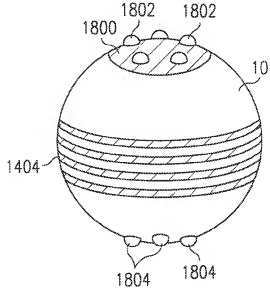
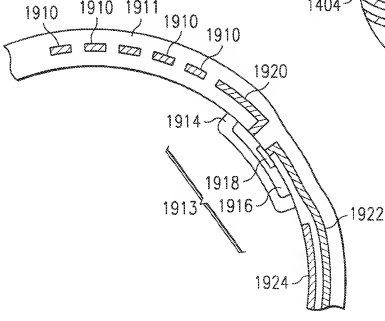


FIG. 19



INTERNATIONAL SEARCH REPORT

	national Application No
	PCT/US 99/28024

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00 A61F2/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F G01L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 33513 A (LIPOMATRIX, INC.) 18 September 1997 (1997-09-18)	1,2,4,6, 7,9-11
X	page 5, line 3 -page 6, line 7	22,24
X	page 19, line 10 -page 20, line 13 page 26, line 1 - line 23 page 35, line 9 -page 36, line 2	..5,27
X	US 4 846 191 A (B.P. BROCKWAY ET AL.) 11 July 1989 (1989-07-11)	1,2,4,6, 7
A	column 5, line 5 - line 23 column 6, line 59 -column 7, line 11	10,26

-/—

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 March 2000	27/03/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Rieb, K.D.

Form PCT/ISA/210 (second sheet) (July 1992)

International Application No
PCT/US 99/28024

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 29030 A (BIOSENSE, INC.) 9 July 1998 (1998-07-09)	1,3,4,6, 7,9-11
X	page 1, line 10 - line 28	19,23
X	page 4, line 1 -page 5, line 32 page 6, line 27 -page 7, line 19 page 8, line 30 -page 9, line 4 page 16, line 31 -page 18, line 3	26,27
X	WO 83 03348 A (J&P COATS, LTD.) 13 October 1983 (1983-10-13)	1,4,7, 12,14-16
X	page 1, line 23 -page 3, line 6	23,26
A	WO 98 25090 A (AAKI SEMICONDUCTOR INC.) 11 June 1998 (1998-06-11)	2,9-11, 24,25
	page 25, line 7 -page 26, line 20	
P,X	EP 0 897 690 A (RIJKSUNIVERSITEIT LEIDEN) 24 February 1999 (1999-02-24)	1,2,4,6, 7,9-12
X	column 4, line 16 - line 48	26,27
A	column 5, line 13 - line 55 column 6, line 50 -column 7, line 7	3
P,X	WO 99 26530 A (G.E. CIMOCHOWSKI ET AL.) 3 June 1999 (1999-06-03)	1-4,6,7, 9-12
X	page 11, line 7 - line 27	14-16
X	page 17, line 15 -page 18, line 31 page 31, line 13 - line 34 page 33, line 9 -page 35, line 29	23,26,27

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/28024

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9733513 A	18-09-1997	US 5833603 A	10-11-1998
		AU 2401597 A	01-10-1997
		BR 9707974 A	27-07-1999
		CA 2248965 A	18-09-1997
		EP 0888079 A	07-01-1999
US 4846191 A	11-07-1989	CA 1317482 A	11-05-1993
		DE 68923703 D	07-09-1995
		DE 68923703 T	04-04-1996
		EP 0417171 A	20-03-1991
		JP 2972251 B	08-11-1999
		JP 3504563 T	09-10-1991
		KR 130834 B	20-04-1998
		WO 8911244 A	30-11-1989
WO 9829030 A	09-07-1998	AU 5338698 A	31-07-1998
		CA 2247943 A	09-07-1998
		EP 0904009 A	31-03-1999
WO 8303348 A	13-10-1983	DK 531883 A	21-11-1983
		EP 0103608 A	28-03-1984
		ES 520933 D	16-03-1984
		ES 8403311 A	16-06-1984
		GR 77132 A	07-09-1984
		JP 59500552 T	05-04-1984
WO 9825090 A	11-06-1998	US 5955776 A	21-09-1999
		AU 4161497 A	29-06-1998
		EP 0951631 A	27-10-1999
		US 6004396 A	21-12-1999
		US 5945725 A	31-08-1999
EP 897690 A	24-02-1999	NONE	
WO 9926530 A	03-06-1999	US 5967986 A	19-10-1999
		AU 1363799 A	15-06-1999